REMARKS

Claims 1-32 stand pending in the application and claims 1-3 and 5-32 stand rejected in the non-final Office Action while claim 4 stands objected to.

Applicant herewith amends independent claims 1 and 17 and dependent claim 3, no claims are canceled and no new claims are added.

Applicant respectfully requests entry and favorable consideration of the amendments and remarks presented herewith.

Claim Rejections Based on Double Patenting

Claims 17-20, 25, 26, and 30-32 stand provisionally rejected under the judicially-created doctrine of obviousness-type double patenting over claims 7-9 of copending application no. 09/775,281 and claims 1-3, 5-21, 23-26 and 30-32 stand rovisionally rejected under the judicially-created doctrine of obviousness-type double patenting over claims 7-9 of copending application no. 09/775,262.

Applicant herewith tenders a revised Terminal Disclaimer per the Examiner's suggestion and specifically rescinds the Terminal Disclaimer executed 18 February 2004.

Claim Rejections Based on 35 U.S.C. §112

Claim 3 stands rejected under 35 U.S.C. §112, second paragraph due to a lack of antecedent basis for "the software means."

Applicant herewith amends claim 3 to resolve this ground of rejection by deleting "means" and inserting in lieu thereof "components."

According, having addressed this ground of rejection, Applicant request withdrawal of the rejection of claim 3.

Claim Rejections Based on 35 U.S.C. §102

Claims 1-3 and 5 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Pat. No. 6,497,655 to Linberg et al. (Linberg).

Applicant respectfully traverses this ground of rejection.

First of all, the presently claimed invention contains at least one claim limitation not found, directly or by principles of inherency, in Linberg. Linberg appears directly almost solely to subject matter involving remote monitoring, remote-dispatch of alert signals, remote diagnostic techniques, and related communication links. Applicant suggests that the title of Linberg indicates the focus thereof: "Virtual Remote Monitor, Alert, Diagnostics and Programming for Implantable Medical Device Systems."

Furthermore, Linberg only invokes the term "manufacture" (including variants thereof) and even then only in the following two paragraphs which further provide context for the differences between the presently claimed invention and Linberg:

> Yet a further condition of the prior art relates to the operator-programmer interface. Generally a medical device manager/technician, should be trained on the clinical and operational aspects of the programmer. Current practice requires that an operator attend a class/session sponsored by a clinic, hospital or the **manufacturer** to successfully manage a programmer-IMD procedure. Further, the manager should be able to keep abreast of new developments and new procedures in the management, maintenance and upgrade of the IMD. Accordingly, under current practice it is imperative that operators of programmers, IMDs and related medical devices be trained on a regular basis. (Background Section, Linberg at col 2, lines 8-19)

> As indicated hereinabove, data center 62 represents a high speed computer network system which is located remotely via wireless bi-directional data, voice and video communications with programmer 20 and, in special cases with IMU 20'. Generally data center 62 is preferably located in a central location and is equipped with high-speed web-based, web-enabled or web-compatible computer networks. Preferably, data center 62 is manned 24-hours by operators and clinical personnel who are trained to provide a web-based remote service to programmer 20 and IMU 20' to thereby ensure chronic monitoring, prescriptive programming and implementation of virtual electrophysiological functions remotely. Additionally, as discussed hereinabove, data center 62 includes other resources and features to provide remote monitoring, maintenance and upgrade of programmer 20. The location of remote data center 62 is dependent upon the sphere of service. In accordance with the present invention, data center 62 may be located in a corporate headquarters or **manufacturing** plant of the company that **manufactures** programmer 20. Further, the wireless data and electronic communications link/connection can be one of a variety of links or interfaces, such as a local area network (LAN), an internet connection, a telephone line connection, a satellite connection, a global positioning system (GPS) connection, a cellular connection, a laser wave generator system, any combination thereof, or equivalent data communications links. (col. 15, line 50 to col. 16, line 18)

Applicant thus asserts that Linberg does not provide a solid foundation for a rejection grounded in lack of novelty. Nevertheless, Applicant herewith amends the two independent claims presently being prosecuted herein; namely, claim 1 and claim 17 to more affirmatively claim the present invention, thus traversing this ground of rejection.

Claim Rejections Based on 35 U.S.C. §102

Claims 1-3 and 7-11 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Pat. No. 5,725,599 to Alt et al. (Alt).

Applicant respectfully traverses this ground of rejection.

First of all, the presently claimed invention contains at least one claim limitation not found, directly or by principles of inherency, in Alt. For example, Alt is exclusively concerned with upgrading a basic device by providing *post implant* access to upgraded features resident within the basic device since initial manufacture. Alt neither describes nor depicts any customization during initial manufacture of the device. The basic device is thus not a custom-manufactured device but rather a basic, generically-manufactured device, which is old. It appears that Alt contemplated the perhaps novel subject matter related to non-invasive, restricted access to non-basic features or capabilities *post implant* and including, at least from a device manufacturers perspective, billing or cost-recovery related to the value of the non-invasively upgraded device.

The following excerpt from Alt provides some context for the foregoing assertions (title and abstract):

Programmably Upgradable Implantable Medical Device

> An implantable cardioverter/defibrillator device is **implemented to be selectively non-invasively upgraded** from time to time ***after implantation*** to enable the device to provide additional therapy for arrhythmia treatment as the patient's need for such treatment undergoes change. The device is adapted to provide a plurality of functions corresponding to different levels of therapy for treating arrhythmias, and to respond to each different type of arrhythmia that may be sensed, to supply a function which is designated as being appropriate to relieve that respective arrhythmia. Each function is not necessarily unique to treating a particular arrhythmia, and, in at least some instances, may be used to treat

> more than one of the plurality of different types of arrhythmias. **At the time of its implant, the device is restricted from providing those of the plurality of functions which are deemed as being non-essential** to the patient's needs at that time. From time to time **thereafter**, however, as the patient experiences periodic need for additional therapy, **restricted functions of the device are selectively *restored*** by external programming, but only if the programmer is able to supply to the device an enabling code which is substantially unique to that device. In this way, restoration of the restricted functions is locked out except with a prescribed key. (***emphasis added***.)

Applicant thus believes that Alt does not provide a solid foundation for a rejection grounded in lack of novelty. Nevertheless, Applicant herewith amends the two independent claims presently being prosecuted herein; namely, claim 1 and claim 17 to more affirmatively claim the present invention, thus traversing this ground of rejection.

Claim Rejections Based on 35 U.S.C. §103

Claims 12-23 and 25-32 stand rejected as being unpatentable over Alt in view of U.S. Pat. No. 6,298,443 to Colligan et al. (Colligan).

Applicant respectfully traverses this ground of rejection; at least in part based on the above-noted dissimilarities between the presently claimed invention and Alt, the primary reference applied to reject claims 12-23 and 25-32. Thus, Applicant respectfully asserts that the Examiner has failed to lodge a *prima facie* obviousness rejection and the claims are thus entitled to pass to allowance and, ultimately, to issue as U.S. Letters Patent.

It appears that Colligan simply discloses transporting a CD-ROM with a specific computer wherein the CD-ROM will only work with the specific computer and can be used to restore the specific computer to its original configuration. The title and abstract of Colligan should help clarify the subject matter Colligan addresses:

Method and System for Supplying a Custom Software Image to a Computer System

> A method and system for supplying a software image to a computer system utilize **a custom-programmed compact disk (CD) ROM that is configured for a specified individual computer system** and constrained

> to be downloaded to and operable on only the specified individual computer system. **The method and system further utilize an installation procedure for restoring the specified computer system to the software state that the computer was in at the time the computer left the factory** after initial configuration and downloading. The custom-programmed CD ROM 106 is delivered to a customer in combination with a bootable flexible diskette 108, and an instructional technical instruction sheet for usage by the customer to restore the computer system to a "factory new" software condition.

Furthermore, Applicant respectfully asserts that neither Alt nor Colligan if combined would provide a skilled artisan with the claimed invention. In fact, neither Alt nor Colligan offer any suggestion or motivation to combine, however, if combined the artisan would simply have a basic (or generic) device capable of subsequent "non-invasive" upgrade and which would have the ability, once upgraded (or modified) to return to the original as-manufactured status.

An excerpt from Colligan should help put the foregoing into perspective:

> The users receives the software transfer package and the service kit Technical direction sheet 110 directs the user to execute the restoration program 218 by placing the custom-programmed CD ROM 106 into the computer system CD ROM reader, inserting the bootable flexible diskette 108 in computer system flexible disk drive slot, and rebooting the computer 104. One technique for rebooting the computer 104 is to power down the computer, waiting about thirty seconds, and applying power to the computer 104. **The bootable flexible diskette 108 stores the restoration program that is activated upon bootstrap loading of the computer 104. The execute restoration program act 218 simulates the software download part of the manufacturing process by modifying the master boot record of the hard disk drive 112 to invoke a special restoration operating system.** Special operating system files including .EXE, .BAT, and CONFIG.SYS files are activated to load a CD ROM driver and find the software image 102 on the CD ROM.

Furthermore, Alt fails to disclose or teach any manufacturing customization whatsoever while Colligan contemplates only customization of software for a basic or generic computer system. Also, the software of Colligan ships separately from (e.g., the "software transport package" and the "software transport medium") and Alt offers nothing to the disclosure of Colligan.

For these and the foregoing reasons, Applicant respectfully requests that this ground of rejection be withdrawn.

CONCLUSION

Applicant respectfully asserts that all presently pending claims 1-32 are now in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 13-2546. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Respectfully submitted,

10 Dec. '04
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